IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**MDL NO. 2327**
This case relates to:	
MANDY L. THOMPSON and RICHARD J. AGUIRRE, her husband,	**Case No. 2:17-cv-02208**
Plaintiffs,	
v.	**PLAINTIFFS' RESPONSE TO DEFENDANTS' PARTIAL MOTION FOR SUMMARY JUDGMENT**
ETHICON, INC. and JOHNSON & JOHNSON,	
Defendants.	

Plaintiffs, MANDY L. THOMPSON and RICHARD J. AGUIRRE, by their undersigned attorney, respond to the Motion for Partial Summary Judgment filed herein by the defendants, Ethicon, Inc. and Johnson & Johnson ("Ethicon") on October 16, 2018, and state:

I. STANDARD OF REVIEW

A moving party is entitled to summary judgment "if the movant shows that there is no genuine issue as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Although the court views all underlying facts and permissible inferences in the light most favorable to the nonmoving party, the nonmoving party must offer "concrete evidence from which a reasonable juror could return a verdict in [its] favor." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 256

(1986). "Summary judgment is appropriate when the nonmoving party has the burden of proof on an essential element of his or her case and does not make, after adequate time for discovery, a showing sufficient to establish that element." *McNeely v. Wells Fargo Bank, N.A.*, 115 F. Supp.3d 779, 784 (S.D. W.Va. 2015) (*citing Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986)). The nonmoving party must offer "more than a mere 'scintilla of evidence'" in support of its position. *Id.* (*citing Anderson*, 477 U.S. at 252).

The fundamental principle that reasonable inference should be drawn in favor of the nonmoving party is reaffirmed by the U. S. Supreme Court in *Tolan v. Cotton*, 134 S.Ct. 1861, 1868 (2014), who stated "The witnesses on both sides come to this case with their own perceptions, recollection, and even potential biases. It is in part for that reason that genuine disputes are generally resolved by juries in our adversarial system."

II. STATEMENT OF MATERIAL FACTS

1. On July 19, 2007, Mandy Thompson underwent a hysterectomy and implant of a Gynecare TVT mesh at Central Valley Hospital in Hansford, CA by Robert Ellsworth, DO due to urinary incontinence. (Ex A, PLs Supp Fact Sheet, p. 5)

2. It was Mrs. Thompson's understanding that the purpose of the mesh was to lift her bladder to prevent urinary incontinence. (Ex. B, depo Mrs. Thompson p. 43). At the time she was implanted with the mesh, she did not know that it could cause painful, permanent pain with intercourse. (Id at p. 106)

3. Dr. Ellsworth testified that, at the time of Mrs. Thompson's implant, he did not specifically recall talking to her, but in the normal course of his business he would not have performed surgery without discussing the risks and benefits of the surgery. (Ex. C, depo Ellsworth p. 17). His normal course of business would be to make

sure the patient understood the general risks associated with surgery, including risks with anesthesia, bleeding, damage to surrounding organs such as bladder, bowel, ureter, vaginal tissues and the need for further surgery to correct those issues. (Ex C, depo Ellsworth p. 16-17). It was also his practice to go over the risks associated with the Informed Consent for surgery (Id at 20-22) (Ex D – Thompson Informed Consent). At the time Dr. Ellsworth implanted the TVT in 2007, he felt confident that it was safe and effective. (Id at p.33).

4. In addition, if a brochure was available, it would have been common for him to give it to the patient. (Ex C, depo Ellsworth p. 45). However, when he was presented by defense counsel with a brochure listing certain contraindications, warnings and precautions and adverse reactions, Dr. Ellsworth testified that that brochure was not the one that he had. (Id at p. 46)

5. Dr. Ellsworth testified that he was confident that he implanted the mesh properly. (Ex C, depo Ellsworth p. 62) He also testified that he did read the Instructions for Use (IFU) the first time he used a new device, but did not read the same IFU every time thereafter. (Id at p. 52).

6. Dr. Ellsworth testified that he conveyed to Mrs. Thompson all of the risks of which he was aware at the time of the implant (Ex. C depo Ellsworth p. 63), but he did not know of the risk of scarring or dyspareunia. He was NOT aware of the risk of scarring by the mesh and was NOT aware of the risk of pain with intercourse. (Id at p. 46-47). He also testified that it was his understanding that any foreign body reaction was transitory per the IFU in effect in 2007. (Id at p. 64-65).

7. Neither the TVT Brochure nor the TVT IFU that were in effect in 2007

when Mrs. Thompson was implanted with the product mentioned a risk of chronic foreign body reaction, or scarring, or pain with intercourse. (Ex. E - TVT Brochure)(Ex. F - TVT IFU).

8. In 2015, Mrs. Thompson began to seek treatment for urinary urgency and pain during sex. (Ex. B, depo Mrs. Thompson p. 62). She was referred to a urologist, John Lavelle, MD, who noted that her mesh had eroded into her vagina and he could see it. At that time, Dr. Lavell recommended excision of the eroded mesh. (Id at p. 65)

9. On November 19, 2016, Mrs. Thompson underwent excision of a portion of the eroded mesh at the Palo Alto VA Hospital in Palo Alto, CA by Dr. Lavelle due to persistent dyspareunia, and worsening incontinence. (Ex. B. depo Mrs. Thompson, p. 72-73) (Ex. A, PLs Supp Fact Sheet p 12-13)

10. Soon after that excision surgery, Mrs. Thompson began to experience increasing stress urinary incontinence and a sharp pain in her urethra and bladder area. (Ex. B depo Mrs. Thompson p. 74-76). She then went to Craig Comiter, MD, a urologist, for persistent pain and dyspareunia. Dr. Comiter told her that she had a "ball of mesh" which was the source of her pain and dyspareunia and it needed to be removed. (Id at p. 78).

11. On October 9, 2017, she underwent a 2nd revision surgery at Stanford Hospital by Dr. Comiter for continuing dyspareunia and continuing pelvic pain. Dr. Comiter removed the right-sided mesh. (Ex.G, op report of Dr. Comiter dated 10/9/17).

12. Since the 2nd revision surgery, Mrs. Thompson continues to have pain in her bladder and urethra and her urinary incontinence is uncontrollable. (Ex. B, depo Mrs. Thompson p. 82-84). She is anxious, depressed, and disheartened that she is unable to be

intimate with her husband and fears that he may leave her because of her inability to engage in sex. (Id at p. 91-93)

13. Mrs. Thompson did not experience dyspareunia prior to her implant of the TVT mesh. (Ex. B depo Mrs. Thompson p. 106)

14. Plaintiffs agree that this case is governed by California law.

III. ARGUMENT

1) Plaintiffs' claim for negligent misrepresentation (Count VII) by Defendants raise questions of material fact which must be decided by a jury.

Defendants do not contest the viability of Plaintiffs' claims for negligent design (Count I), strict liability failure to warn (Count III) or negligent failure to warn (Count I). This is significant because California law prohibits a failure to warn claim concerning a prescribed medical device unless the plaintiff can show that the warnings provided by the manufacturer to the prescribing physician about dangers known to the manufacturer were inadequate, and the inadequate warnings altered the physician's decision to prescribe the treatment. *Sanchez v. Boston Scientific Corp*., 38 F.Supp. 3d 727, 734 (SD W.Va 2014). Defendants contend, however, that Plaintiffs' negligent misrepresentation is merely duplicative of their failure to warn claim.

Defendants knew since 2004 when the TVT was cleared for market that the TVT polypropylene mesh was associated with adverse events such as erosions through the vaginal epithelium, infection, pain, urinary problems, dyspareunia, the need for additional surgeries and/or the need for removal of the device, urinary tract infections, dysuria, denovo urgency, mesh exposure, fistula formation, abscess formation, scarring, contracture of the mesh causing pain, and complications making it impossible to have sexual relations, and worsening incontinence. (Ex. H, excerpt of Report of Bruce Rosenzweig, MD August 24, 2015 at 73-74, 99-101.) Despite that knowledge, the TVT IFU, specifically the IFU that was provided to Dr.

Ellsworth in this case, contained the same Adverse Reactions/Risks section that had been published without change from May, 1999 to May, 2015, and read as follows:

- "Punctures or lacerations of vessels, nerve, bladder or bowel may occur during needle passage and may require surgical repair;
- Transitory local irritation at the wound site and transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.
- As with all foreign bodies, PROLENE Mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE Mesh is designed to minimize the risk of contamination;
- Over correction, i.e., too much tension applied to the tape may cause temporary or permanent lower urinary tract obstruction." (Ex. F – TVT IFU).

In addition, the brochure that was in effect and that may have been given to Mrs. Thompson loudly represented:

- One-time minimally invasive 30-minute procedure
- The only procedure of its type with 7 years of proven results – clinically proven, safe and effective.
- 98% of women treated with GYNECARE TVT are still dry or report significantly less leakage seven years after treatment."

The Brochure contained only two Adverse Reactions in very small print:

- Punctures or lacerations or injury to vessels, nerve, bladder, ureter, or bowel may occur during instrument passage and may require surgical repair.
- Improper placement of the TVT device may result in incomplete or no relief from urinary incontinence or may cause urinary tract obstruction.

In other words, only if the device is improperly implanted, might there be any adverse effects at all.

The adverse effects that Mrs. Thompson suffers are hardly transitory. She is left with chronic uncontrollable urinary incontinence and chronic pain with sex, which impairments have caused her severe anxiety and depression, and fear that her husband will leave her. Unfortunately, as Dr. Ellsworth testified, he did NOT know that it would cause chronic pain and did NOT know it would cause dyspareunia, and did NOT know it would cause scarring because of quality, safety and efficacy of the device had been misrepresented to him.

Defendants present no evidence that Dr. Ellsworth would not have warned Mrs. Thompson of the risks of *permanent, chronic pelvic pain* and *permanent pain with sex* if he had been made aware of those risks. On the contrary, Dr. Ellsworth testified that he conveyed all of the risks of which he was aware to Mrs. Thompson (Ex C, depo Ellsworth p. 63), but he did not know of the risk of scarring or dyspareunia (Id at p. 47), and understood that any foreign body reaction was transitory per the IFU that was available at the time (Id at p. 64-65).

Defendants' misrepresentations and omissions prevented him from sharing the full list of risks and adverse effects with her. Mrs. Thompson reasonably relied upon Dr. Ellsworth's recommendations and descriptions of the risks which he had been provided when she agreed to the TVT procedure, and was severely injured by chronic pain, chronic dyspareunia, and scarring – warnings that were NOT included, as a result. In light of the vast discrepancy between what Ethicon knew and what it shared with implanting physicians, Plaintiffs' claim for negligent misrepresentation must stand. At the very least, there is sufficient evidence to take this issue to a jury.

SUMMARY

Plaintiffs cede their claims in as to negligent manufacturing (part of Count I), as to strict liability manufacturing defect (Count II), strict liability defective product (Count IV), fraudulent concealment (Count VII), and Count XV (unjust enrichment).

Plaintiffs dispute Defendants' argument as to the Negligent Misrepresentation claim (Count X) because Plaintiffs have shown clear evidence that defendants not only failed to provide adequate evidence to Plaintiff's implanting physician, but also affirmatively represented that the product was much better and safer than it actually was

despite prior knowledge to the contrary. In light of that, Plaintiffs' claim for negligent misrepresentation (Count X) should stand as a triable issue.

The remainder of Plaintiffs' claims, which were not contested by the Defendants, including negligent design and negligent failure to warn (Count I), strict liability failure to warn (Count III), loss of consortium (Count XVI) and Punitive Damages Count XVII) raise sufficient questions of fact for a jury to determine.

CERTIFICATE OF SERVICE

I CERTIFY that on October 25, 2018, the foregoing document was filed with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL, and copies of same were furnished by e-mail to the following counsel for defendants:

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